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| EXAMINER | |
|---|---|
| PHAM, AUDREY S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/772,656 | SAUS ET AL. | |
| | Examiner | Art Unit | |
| | Audrey S. Pham | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Re: Saus *et al.*

Claims 1-33 are pending.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 11, 23, 25, 32-33 drawn to a substantially purified polypeptide comprising an amino acid sequence and to a pharmaceutical composition thereof, classified in class 530, subclass 300.

**NOTE: Upon election of Group I above, Applicant must further elect ONE amino acid sequence according to the SEQ ID NOs listed in Claims 1-7, 23, 32-33 as each amino acid sequence represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

II. Claims 8, 16, 19, drawn to a substantially purified polypeptide comprising an amino acid sequence, classified in class 530, subclass 350.

**NOTE: Upon election of Group II above, Applicant must further elect ONE polypeptide comprising either a SEQ ID NO listed in Claims 8, 16, 19 and -- if applicable -- ONE a GPBP polypeptide listed in Claim 16 as each peptide represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

III. Claim 9, drawn to a substantially purified polypeptide, wherein the polypeptide comprises an amino acid sequence according to the genus R1-R2-R3, classified in class 530, subclass 350.

IV. Claim 10, drawn to a substantially purified polypeptide, wherein the polypeptide comprises an amino acid sequence according to the genus X1-X2, classified in class 530, subclass 350.

V. Claims 12, 14, drawn to an antibody that selectively binds to the polypeptide comprising an amino acid sequence but which does not selectively bind to SEQ ID 104, classified in class 530, subclass 387.1.

**NOTE: Upon election of group V above, Applicant must further elect ONE amino acid sequence according to the SEQ ID NOs listed in Claims** 12 and 14 **as each amino acid sequence represents a separate group. Note this is not an election of species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

VI. Claim 13, drawn to a method for making an antibody selectively for one or more non-canonical Goodpasture antigen binding protein isoforms, comprising immunizing a host animal with an antigen derived from a polypeptide consisting an amino acid sequence, classified in class 435, subclass 69.2.

**NOTE: Upon election of group VI above, Applicant must further elect ONE polypeptide listed in Claim 13 (which includes either a SEQ ID NO or a GPBP polypeptide) as each peptide represents a separate group. Note this is not an election of species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

VII. Claim 15, drawn to a method for detecting the presence of a protein that is substantially similar to one or more polypeptides comprising an amino acid sequence, classified in class 435, subclass 7.1.

**NOTE: Upon election of Group VII above, Applicant must further elect ONE polypeptide listed in Claim 15 (which includes either a SEQ ID NO or a GPBP polypeptide) as each peptide represents a separate group. Note this is not an election of species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

VIII. Claims 17-18, drawn to a method of making a substantially purified processed GPBP polypeptide comprising providing cells that express one or more polypeptide, lysing the cells and isolating one or more fractions of the cells contacting the isolated fraction with an immunoaffinity comprising an antibody

that selectively binds to a polypeptide under conditions that result in binding of a GPBP to the immunoaffinity column and isolating a substantially purified GPBP, classified in class 435, subclass 70.1.

**NOTE: Upon election of Group VIII above, Applicant must further elect ONE polypeptide listed in Claims 17-18 and ONE resulting GPBP polypeptide or a recombinant polypeptide as each peptide combination represents a separate group. Note this is not an election of species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

IX. Claims 20-21, drawn to a method for identifying candidate compounds to treat an autoimmune condition or a protein deposit-mediated disorder comprising incubating a target polypeptide with a GPBP isoform comprising one amino acid sequence under conditions that promote phosphorylation of the target polypeptide by the GPBP isoform, classified in class 435, subclass 4.

**NOTE: Upon election of Group IX above, Applicant must further elect ONE polypeptide from α3(IV)NC1 domain, MBP or prion and one GPBP isoform (which includes either a SEQ ID NO or a GPBP polypeptide) as each polypeptide combination represents a separate group. Note this is not an election of species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

X. Claims 20-21, drawn to a method for identifying candidate compounds to treat an autoimmune condition or a protein deposit-mediated disorder comprising incubating a target polypeptide with a GPBP isoform comprising one amino acid sequence under conditions that promote autophosphorylation of the GPBP isoform, classified in class 435, subclass 4.

**NOTE: Upon election of Group X above, Applicant must further elect ONE polypeptide listed in Claims 20-21 (which includes either a SEQ ID NO or a GPBP polypeptide) as each peptide represents a separate group. Note this is not an election of species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

XI. Claims 20-21, drawn to a method for identifying candidate compounds to treat an autoimmune condition or a protein deposit-mediated disorder comprising incubating a target polypeptide with a GPBP isoform comprising one amino acid

sequence under conditions that promote conformational isomerization of the target polypeptide, classified in class 435, subclass 4.

**NOTE: Upon election of group XI above, Applicant must further elect ONE polypeptide from α3(IV)NC1 domain, MBP or prion and one GPBP isoform (which include either a SEQ ID NO or a GPBP polypeptide) as each polypeptide combination represents a separate group. Note this is not an election of species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

XII. Claims 20-21, drawn to a method for identifying candidate compounds to treat an autoimmune condition or a protein deposit-mediated disorder comprising incubating a target polypeptide with a GPBP isoform comprising one amino acid sequence under conditions that promote formation of an interaction between the GPBP isoform and the target polypeptide, classified in class 435, subclass 7.23.

**NOTE: Upon election of group XII above, Applicant must further elect ONE polypeptide listed in Claims 20-21 (which includes either a SEQ ID NO or a GPBP polypeptide) as each peptide represents a separate group. Note this is not an election of species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

XIII. Claims 22, 24, drawn to an isolated polypeptide consisting of Xi-SHCIX2-X3 and to a pharmaceutical composition thereof, classified in class 530, subclass 300.

XIV. Claims 26-27, drawn to an isolated nucleic acid and to a pharmaceutical composition comprising the nucleic acid thereof, classified in class 536, subclass 23.1.

**NOTE: Upon election of group XIV above, Applicant must further elect ONE nucleic acid sequence listed in Claim 26 as each nucleic acid represents a separate group. Note this is not an election of species. Applicant is reminded that any claims not reading on the elected nucleic acid will be withdrawn as being drawn to a non-elected invention.**

XV. Claim 28, drawn to a method of treating a disorder comprising administering to a subject in need thereof an amount effective of the polypeptide consisting of X1-SHCIX2-X3, classified in class 424, subclass 184.1.

XVI. Claim 29, drawn to a method of treating a disorder comprising administering to a subject in need thereof an amount effective of the polypeptide consisting of SEQ ID NO: 45, classified in class 424, subclass 184.1.

XVII. Claim 30, drawn to a method of treating a disorder comprising administering to a subject in need thereof an amount effective of the polypeptide consisting of ONE nucleic acid, classified in class 514, subclass 44.

**NOTE: Upon election of Group XVII above, Applicant must further elect ONE nucleic acid from the SEQ ID NOs listed in Claim 26 as each nucleic acid represents a separate group, not a species. Applicant is reminded that any claims not reading on the elected peptide will be withdrawn as being drawn to a non-elected invention.**

XVIII. Claim 31, drawn to a method of treating a disorder comprising administering to a subject in need thereof an amount effective of to treat the disorder of a compound, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other for the following reasons:

The inventions of groups I-V, XIII-XIV and the methods of groups VI-XII, XV-XVIII are related as products and processes of use. The inventions can be shown to be distinct if one of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case, the polypeptides and the nucleic acid, as claimed, can be used in a materially different process such as in methods of developing binding assays, methods of purification, or methods of making said molecules. Likewise, the antibody, as claimed, can be used in materially different methods such as in methods of developing vaccines, methods of treating cancer or methods of developing a therapeutic inhibitor.

The inventions of groups I-V, XIII-XIV encompass multiply distinct and independent products that encompass different functional as well as structural formulas. Groups I-IV and XIII

encompass specific polypeptides, each is structurally distinct as evident by different amino acid compositions and lengths. Group V encompasses an antibody, and group XIV encompasses an isolated nucleic acid molecule. Each of these groups represent separate and distinct chemical products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polypeptides of groups I-IV and XIII are composed of amino acids whereas the polynucleotide of group XIV is composed of nucleic acids. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The antibody of group V includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). The antibody, polynucleotide and polypeptide inventions have separate statuses in the art as shown by their different classifications. Searching the inventions of all the groups would impose a substantial burden because a search of the invention of one group would not be used to determine the patentability the other groups.

While the inventions of groups I-IV all relate to polypeptides, they are patentably distinct products – each from the others. Each of the polypeptides of groups I-IV represents a different molecule with its own distinct 2- and 3- dimensional folding patterns, distinct functions and distinct biological activities. Even though the polypeptides may share a segment of amino acid residues (SEQ ID NO: 29) that is identical with the others, the actual segment that is shared by the polypeptides make up a very low percentage of the overall sequence of any particular polypeptide of the different invention groups. The structural and functional characteristics of a polypeptide are dictated by the overall makeup of the entire amino acid sequence, rather than the short segment one polypeptide has in common with the others. The inventions of groups I-IV comprise of polypeptides of different lengths and composition, giving rise to structurally and functionally distinct molecules. Also, each group encompasses multiple polypeptide sequences. As such, the polypeptide(s) of one group could not be substituted for the others. Because each polypeptide is distinct, a different search is required for the determination of patentability for each of the polypeptide groups. Currently, there are approximately eight different databases that accompany the results of a search of one discrete amino acid sequence and each result set from each database must be carefully considered. Searching the inventions of all the groups

would impose a substantial burden because a search of the invention of one group would not be used to determine the patentability the other groups.

The inventions of groups VI-XII, XV-XVIII are materially distinct methods, which differ at least in objectives, method steps and reagents. Group VI is drawn to a method of making an antibody, group VII is drawn to a method for detecting the presence of a protein, group VIII is drawn to making a GPBP polypeptide, groups IX-XII are drawn to methods of identifying candidate compounds and groups XV-VXIII are drawn to methods of treating a disorder. Each of the groups employs chemically distinct reagents to accomplish the various objectives or even the same objective. For example, groups IX-XII are drawn to methods of identifying candidate compounds to treat an autoimmune condition or a protein deposit-mediated disorder but each group differs in the reagents, steps and conditions they use to identify candidate compounds: group IX comprises identifying a compound under conditions that promote phosphorylation of the target polypeptide by the GPBP isoform; group X comprises identifying a compound under conditions that promote autophosphorylation of the GPBO isoform; group XI comprises identifying a compound under conditions that promotes conformational isomerization of the of the polypeptide and group X comprises identifying a compound under conditions that promote the formation of an interaction between the GPBP isoform and the target polypeptide. Searching the inventions of all the groups would impose a substantial burden because a search of the invention of one group would not be used to determine the patentability the other groups.

These inventions are distinct for the reasons given above and they have acquired separate statuses in the art as shown by their different classifications. The search required for one group is not required for the other groups and vice versa. For these reasons, restriction for examination purposes as indicated is proper.

Applicant is reminded that, for a reply to this requirement to be completed, a reply must include an election of the invention to be examined even though the requirement is traversed (See 37 CFR 1.143).

***Species Election***

One or more of the above invention groups contain multiple generic claims that include a plurality of alternatively usable substances or members. These alternative limitations are independent or distinct inventions such that they do not share a common utility or share a substantial structural feature disclosed as being essential to that utility. Because they are not so closely related, a search and examination of the entire claim cannot be made without undue burden. The members of the alternative groupings are described in the following:

Group II (Claim 16) is generic to a plurality of disclosed patentably distinct species comprising the following cell organelles of the liver tissue: cytoplasm, mitochondria, microsomes, and lysosomes.

The products of the above species represent separate and distinct organelles with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and consideration of different patentability issues.

Group VIII (Claim 17) is generic to a plurality of disclosed patentably distinct species comprising the following fractions: cytoplasmic-containing fractions, mitochondrial-containing fractions, microsomal-containing fractions and lysosomal-containing fractions.

The products of the above species represent separate and distinct fractions comprising different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and consideration of different patentability issues.

Groups IX-XII, XV-XVIII (Claims 20-21, 28-31) are generic to a plurality of disclosed patentably distinct species comprising the following disorders (listed in the specification): Goodpasture Syndrome, multiple sclerosis, systemic lupus erythematosus, cutaneous lupus erythematosus, pemphigus, pemphigoid, lichen planus, Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis, prion diseases, type II diabetes, and autoimmune disorders.

The symptoms of the above species represent separate and distinct conditions that differ at least in etiology, pathology, and mechanisms. As such, each species would require different searches and the consideration of different patentability issues.

Group XVIII (Claim 31) is generic to a plurality of disclosed patentably distinct species comprising the following compounds: staurosporine, Ca.sup.2+CaM, 1-[N,O-bis-(5-Isoquinolinesulfonyl)-N-methyl- -L-tyrosyl]-4-phenylpiperazine (KN62), and 2-[N-(2-hydroxyethyl)-N-(4-meth- oxybenzenesulfonyl)]amino-N-(4-chlorocinnamyl)-N-methylbenzylamine (KN-93), or pharmaceutically acceptable salts thereof.

The products of the above species represent separate and distinct compounds with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Upon election of group II, VIII, IX-XII, XV-XVII or XVIII, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

***Rejoining Claims***

NOTE:

The Examiner has required restriction between product and process claims. Where Applicant elects claim(s) directed to a product and the product claim(s) is/are subsequently found allowable, the withdrawn process claim(s) that depend(s) from or otherwise include all the limitations of the allowable product claim(s) will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if an amendment is presented prior to a final rejection or allowance, whichever is earlier. Amendment submitted after final rejection is governed by 37 CFR 1.116; amendment submitted after allowance is governed by 37 CFR 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claim(s) and process claim(s) may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the withdrawn process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Inventorship Amendment***

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended to be in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request, as set forth in 37 CFR 1.48(b), and by a processing fee, as set forth in 37 CFR 1.17(i).

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Audrey S. Pham whose telephone number is (571) 272-3323. The examiner can normally be reached during the hours of 8:30 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached during business hours at the telephone number: (571) 272-0787. The fax number for the organization, where this application or proceeding is assigned, is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Audrey S. Pham
Patent Examiner
Art Unit 1642

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER